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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KRUSE, DAVID H	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/686,234	SOMERVILLE ET AL.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 October 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-8, in Paper No. 21, filed 25 April 2003 is acknowledged. The traversal is on the ground(s) that all of the groups are related in that they are all mutants of the same cellulose synthase gene.

The Examiner has reconsidered the restriction requirement and withdraws said requirement. All of the pending claims will be examined.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR § 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. The first sentence of the specification refers to Provisional Application No. 60/159,369, but does not contain a specific reference as to a claim of benefit to said provisional application. Amendment is required. See MPEP § 201.11, Reference to First Application (8th ed., August 2001).

Drawings

3. The corrected or substitute Figure 2 was received on 13 February 2003. This drawing is not acceptable and appears informal. Applicant is reminded that correction

of the drawings cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will be considered non-responsive to this Office action. Original Figure 1 is acceptable.

4. The Examiner notes that the original Figure 2 in the file was presented as a color drawing. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR § 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR § 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Specification

5. The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. The

Examiner notes that embedded hyperlinks were also presented in the Preliminary Amendment filed 13 February 2003. Appropriate correction is required.

Claim Objections

6. Claims 3-7, 9-11, 13-15 and 16-19 are objected to because of the following informalities:

At claims 3 and 4, the phrase "a plant cell" should read -- the transgenic plant cell -- in referring to claim 2.

At claim 5, the phrase "a transgenic plant" should read -- the transgenic plant -- in referring to claim 4.

At claim 6, the phrase "A transgenic plant cell" should read -- The transgenic plant cell -- in referring to claim 2.

At claim 7, the phrase "an *Arabidopsis*" should read -- the *Arabidopsis* -- in referring to claim 6.

Claim 9 is objected to because at line 3, the use of the abbreviation "CS" appears to be directed to cellulose synthase, but there is no clear indication within the claim of the abbreviation's meaning. See also claim 15, line 3.

At claim 10, line 3, the phrase "a cellulose synthase gene" should read -- the cellulose synthase gene -- in referring to claim 9.

At claim 11, the phrase "A transgenic plant cell" should read -- The transgenic plant cell -- in referring to claim 10.

At claim 13, the phrase "A transgenic plant cell" should read -- The transgenic plant cell -- in referring to claim 10.

At claim 14, the phrase "a transgenic plant cell" should read -- the transgenic plant cell -- in referring to claim 10.

At claim 16, line 3, the phrase "a cellulose synthase gene" should read -- the cellulose synthase gene -- in referring to claim 15.

At claim 17, the phrase "A transgenic plant cell" should read -- The transgenic plant cell -- in referring to claim 15.

At claim 18, the phrase "A transgenic plant cell" should read -- The transgenic plant cell -- in referring to claim 15.

At claim 19, the phrase "a transgenic plant cell" should read -- the transgenic plant cell -- in referring to claim 15.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1, 9 and 15 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The mutant gene claimed in claims 1, 9 and 15 does not indicate the hand of man and reads on a product of nature, which is not statutory subject matter. Amending claims 1, 9 and 15 to read -- An isolated mutant gene -- would obviate this rejection.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. These claims are omnibus type claims. See MPEP § 2173.05(r). Claims 3-7 are also indefinite because they are ultimately dependent upon claim 2 and do not obviate the indefiniteness of claim 2.

Claims 1, 2 and 8 are indefinite because said claims contain variable limitations that do not set forth the metes and bounds of the invention, specifically the references to GENBANK access numbers AF027174 and AB018111, which are subject to change.

At claim 5, line 1, the limitation "derived from" as directed to the transgenic plant according to claim 4 renders the claim indefinite because it is unclear what the metes and bounds of "derived from" are in the instant case. Amending the claim to recite -- isolated from the transgenic plant according to claim 4 -- would obviate this rejection.

At claim 7, line 1, the limitation "derived from" as directed to "an *Arabidopsis* plant cell according to claim 6" renders the claim indefinite because it is unclear what the metes and bounds of "derived from" are in the instant case. Amending the claim to recite -- isolated from a plant regenerated from the *Arabidopsis* plant cell according to claim 6 -- would obviate this rejection.

Claim 9 is indefinite because at line 2, the limitation "having an amino acid substitution at residue 998" appears to be a relative limitation as directed to a mutant gene encoding a cellulose synthase, hence does not state the metes and bounds of the claimed invention. Claims 10-14 are also indefinite because said claims do not obviate the indefiniteness of claim 9.

Claim 12 is indefinite because at line 1, the phrase "a transgenic plant" lacks proper antecedent basis in claim 10. Amending the claim as outlined in the rejection of claim 7 would obviate this rejection.

Claim 15 is indefinite because at line 2, the limitation "having an amino acid substitution at residue 942" appears to be a relative limitation as directed to a mutant gene encoding a cellulose synthase, hence does not state the metes and bounds of the claimed invention. Claims 16-21 are also indefinite because said claims do not obviate the indefiniteness of claim 15.

Claims 17-19 are indefinite because the limitation "A(a) transgenic plant cell" lacks proper antecedent basis in claim 15.

Claim 20 is indefinite because the limitation "a transgenic plant" lacks proper antecedent basis in claim 15. In addition, the limitation "derived" is indefinite for the reasons given for claim 7.

At claim 21, line 4, the phrase "producing a viable seed according to claim 20" is indefinite because claim 20 is a product claim and is not directed to a method of producing a viable seed, conversely, said phrase is indefinite because it does not set

forth any method steps by which one of skill in the art is to produce a viable seed, hence the metes and bounds of the claimed method are unclear.

11. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-21 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At claims 1-8, Applicant claims a mutant gene which codes for a herbicide resistant cellulose synthase having the herein described nucleotide changes in the sequence of GENBANK accession numbers AF027174 and AB018111, a transgenic plant comprising said mutant gene and a tissue culture comprising an expression cassette comprising said mutant gene. The instant claims lack adequate written description because the GENBANK disclosures are subject to modification outside of the Applicant's influence and hence do not describe the claimed invention (claims 1, 2 and 8). Case in point is that GENBANK accession number AB018111 has undergone multiple revisions since it's first public disclosure on 6 October 1998 and since Applicant's filing, a copy of the "Sequence Revision History" is attached hereto. Applicant cannot rely upon this public database disclosure to describe the claimed invention.

At claims 9-21, Applicant claims a mutant gene encoding (an) isoxaben and thiazolidinone-resistant cellulose synthase having an amino acid substitution at residue 998 from glycine to aspartic acid, or at residue 942 from threonine to isoleucine. Applicant also claims a transgenic plant cell, a viable seed, a transgenic plant and a method of producing a transformed crop plant comprising said mutant gene(s).

Applicant describes a putative *Arabidopsis thaliana* cellulose synthase IXR1 gene, comprising one of two point mutations that encode the claimed amino acid substitutions, in SEQ ID NO: 1 and 2.

Applicant does not describe other cellulose synthase genes encoding the described point mutations that confer isoxaben and thiazolidinone herbicide-resistance as broadly claimed.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a

recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

13. Claims 1, 9 and 15 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising the nucleotide sequence taught in SEQ ID NO: 1 and SEQ ID NO: 2, does not reasonably provide enablement for any isolated nucleic acid encoding a cellulose synthase comprising an amino acid substitution at residue 998 from glycine to aspartic acid, or at residue 942 from threonine to isoleucine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's claims are discussed supra.

What Applicant teaches is discussed supra.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance on how to make and use nucleic acids that encode a cellulose synthase comprising an amino acid substitution at residue 998 from glycine to aspartic acid, or at residue 942 from threonine to isoleucine as broadly

claimed. At the time of Applicant's invention, the art teaches that the mechanisms that plants use in synthesis of cellulose have not yielded to biochemistry or cloning by hybridization to genes encoding prokaryotic cellulose systems, and that both the putative cotton cellulose synthase gene and the *Arabidopsis* RSW1 (syn. GENBANK accession no. AF027174) have been proposed to encode the catalytic subunit of the cellulose synthase complex by indirect methods using mutant complementation and similarity to the β-glycosyl transferase super-family of enzymes (see Arioli *et al* 1998, Science 279:717-720). The art teaches that although putative cellulose synthase encoding nucleic acids have been isolated, expression of these nucleic acids is heterologous organisms has not been show to produce cellulose, let alone shown to have glycosyltransferase activity, which would be required to use the claimed mutant genes, and that the expression of other necessary genes appears to be also required to allow functional expression of cellulose synthase gene in heterologous systems (Holland *et al* 2000, Plant Physiology 123:1313-1323, see page 1320, right column). In addition, even though the heterologous systems mentioned by Holland *et al* are non-plant, it is unclear from the teachings of the art that a cellulose synthase encoding nucleic acid from one plant will properly function in a heterologous plant without empiric evidence.

Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to screen through a myriad of putative cellulose synthase encoding nucleic acids, produce the claimed mutations in the coding

sequence to identify those nucleic acid that would encode resistance to isoxaben and thiazolidinone as broadly claimed.

14. Claims 2-9, 10-14 and 16-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claimed invention and Applicant's teachings are discussed supra.

The teachings of Wands are outlined above.

Applicant has no reduced to practice the claimed transgenic plant cell or plant having resistance to a level of isoxaben and thiazolidinone, which prevents or inhibits the growth of a wild-type plant, including *Arabidopsis*. The art, at the time of Applicant's invention, does not teach that transforming heterologous plant with a nucleic acid encoding a putative cellulose synthase enzyme and producing a functional enzyme is predictable (Holland *et al* 2000, cited above). The art, at the time of Applicant's invention, does not teach that isolation of nucleic acids encoding cellulose synthase enzymes, especially the catalytic subunit of the cellulose synthase complex, is a predictable art. The art teaches the need for caution in using sequence similarity to infer function based on sequence and that it was not known, at the time of Applicant's invention, whether other polypeptides are also required for cellulose synthase activity (Richmond and Somerville 2000, Plant Physiology 124:495-498, see page 495, left column and page 497, right column). Hence, the art teaches that the art was not

predictable at the time of Applicant's invention to make and use isolated nucleic acids encoding the catalytic subunit of the cellulose synthase complex as broadly claimed, and it would have required undue trial and error experimentation to isolate said nucleic acids, make the claimed modifications in the coding sequences and transform a myriad of plant to identify those that are isoxaben and thiazolidinone resistant, in addition to having to isolate other nucleic acids encoding polypeptides required for function and transforming plant as suggested by the art.

Claims 6 and 7 lack adequate enablement because of the issue outlined above as directed to claim 2 under written description. Claims 6 and 7 would be enabled for transgenic *Arabidopsis* plants transformed or comprising an isolated nucleic acid that encodes the polypeptide encoded by SEQ ID NO: 1 or SEQ ID NO: 2.

See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.".

Conclusion

15. The claims are free of the prior art, which neither teaches nor fairly suggests an isolated cellulose synthase gene encoding an herbicide resistant cellulose synthase having the taught amino acid substitution, nor does the art teach plants transformed with a mutant cellulose synthase gene.

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
28 July 2003